

	ORA-WIDE POLICY FDA OFFICE OF REGULATORY AFFAIRS ASSOC. COMMISSIONER FOR REGULATORY AFFAIRS	DOCUMENT #: ORA-QMS-POL.001	VERSION #: 3.0
			PAGE 1 OF 3
TITLE: ORA Mission, Vision and Quality Policy			EFFECTIVE DATE: 2/18/2011

1. Purpose. ORA maintains mission and vision policy statements in alignment with the FDA mission to assist managers and staff in seeing their role in FDA and ORA performance. ORA maintains a “quality policy” to reflect its commitment to producing quality work products and services through an integrated quality management system. This document provides the controlled copy of the ORA vision, mission and quality policy statements. The quality policy statement is maintained in accordance with Section 1.4 of Staff Manual Guide (SMG) 2020.

2. Scope: These statements apply to all ORA units. Units may develop auxiliary statements in alignment with this document and the ORA Strategic Plan.

3. Responsibility:

- (a) The Associate Commissioner for Regulatory Affairs (ACRA) is responsible for the content of this policy statement
- (b) The Executive Director for ORA Strategic Initiatives or designee is responsible for maintaining the official version.
- (c) All ORA employees are responsible for becoming familiar with and adhering to this policy statement.

4. Procedure

Type	(a) The approved statements are	(b) Unofficial shorthand”
(1) Vision	“All food is safe; all medical products are safe and effective; and the public health is advanced and protected.”	“Advancing public health”
(2) Mission	“ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.”	“Protecting and promoting public health”
(3) Quality commitment	“The Office of Regulatory Affairs (ORA) is committed to quality and continual improvement in all of our processes, products and services. The ORA Quality Management System (QMS), in accordance with Staff Manual Guide (SMG) 2020 requirements, is utilized to successfully meet these standards. Significant planning is undertaken to provide the resources and support ORA QMS requires so that the organization successfully meets its Quality Objectives through the active utilization of Quality processes. ORA Senior Management is dedicated to promoting long-term quality management through the continual monitoring and improvement of our work products and services. All activities conducted by ORA employees will strive to meet the quality expectations of our	“Committed to quality and continual improvement, with actions that demonstrate a dedication to effectively meeting our customers’ needs”

 <div>ORA-WIDE POLICY FDA OFFICE OF REGULATORY AFFAIRS ASSOC. COMMISSIONER FOR REGULATORY AFFAIRS</div>	DOCUMENT #: ORA-QMS-POL.001	VERSION #: 3.0
		PAGE 2 OF 3
TITLE: ORA Mission, Vision and Quality Policy		EFFECTIVE DATE: 2/18/2011

	<p>internal and external stakeholders. Through QMS, we as an organization strive to ensure that ORA is as effective and efficient as possible in the pursuit of our Vision that all food is safe, all medical products are safe and effective, and public health is advanced and promoted.”</p>	
--	---	--

(c) The statements may be reproduced with source attribution: document identification number and the appropriate version number (i.e. “ORA-QMS-POL.001 Version 3.0”)

5. Supporting documents:

- ORA-QMS-POL.002-ORA Quality Manual Version 1.3 (Effective Date 2/4/2011)
- FDA Strategic Priorities
- Staff Manual Guide (SMG) 2020 (Effective Date 9/1/06)

6. Records	None.
7. Reference	None.
8. Glossary	None.
9. Attachments	Sample formatted statements

Document history					
VERSION #	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	NAME, TITLE & ORGANIZATION	
				CONTACT	APPROVING OFFICIAL
1.0	initial	10/01/2002	n/a	P.Maroney-Benassi, ORA QMS program manager	Dennis E. Baker, Assoc. Comm. For Regulatory Affairs
2.0	R	02/05/2007	T. Notice ORA-QMS-07-001	P.Maroney-Benassi, ORA QMS program manager	Margaret K. Galvin, Assoc. Commissioner for Regulatory Affairs
2.1	R	09/25/2008	In Document	ORA QMS Staff	Brenda Holman, QMS Executive Lead
3.0	R	02/16/2011	In Document	ORA QMS Staff	Dara Corrigan, Associate Commissioner for Regulatory Affairs

10. Change History:

Version 3.0:

Title changed to “ORA Mission, Vision and Quality Policy”

Purpose- “The quality policy statement is maintained in accordance with Section 1.4 of Staff Manual Guide (SMG) 2020” added

Responsibility- “The Executive Director of ORA Strategic Initiatives or designee is responsible for maintaining the official version” and “All ORA employees are responsible for becoming familiar with and adhering to this policy statement” added

Procedure- Quality commitment statement revised.

Supporting Documents- FDA Strategic Priorities and SMG 2020 added.

 <div>ORA-WIDE POLICY FDA OFFICE OF REGULATORY AFFAIRS ASSOC. COMMISSIONER FOR REGULATORY AFFAIRS</div>	DOCUMENT #: ORA-QMS-POL.001	VERSION #: 3.0
		PAGE 3 OF 3
TITLE: ORA Mission, Vision and Quality Policy		EFFECTIVE DATE: 2/18/2011

Sample Images of ORA Vision, Mission and Quality Commitment statements



FDA Office of Regulatory Affairs

Advancing public health

VISION
All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

Protecting and promoting public health

MISSION
ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

QUALITY COMMITMENT
Committed to quality, dedicated to the customer
ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.

ORA 1.1 V.2.0



FDA Office of Regulatory Affairs

Advancing public health

VISION
All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

Protecting and promoting public health

MISSION
ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

Committed to quality, dedicated to the customer

QUALITY COMMITMENT
ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.

ORA 1.1 V.2.0